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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/617,046	07/14/2000	David E. Honigs	1548-155A	6107

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EXAMINER

KREMER, MATTHEW J

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 01/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/617,046

Applicant(s)

HONIGS ET AL.

Examiner

Matthew J Kremer

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Objections

1. Claim 3 is objected to because of the following informalities: "sets" should be deleted in line 2 and "sets" should be deleted in line 3. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 8 and 16 are rejected under 35 U.S.C. 112, second paragraph, as failing to set forth the subject matter which applicant(s) regard as their invention. Claim 8 recites the limitation "said three fingers" in line 4 in which there is insufficient antecedent basis. Claim 16 recites the limitation "said NIR measurement device" in line 5 in which there is insufficient antecedent basis.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,077,476 to Rosenthal (cited by Applicant) in view of U.S. Patent 5,313,941 to Braig et al., and further in view of U.S. Patent 5,752,512 to Gozani. Rosenthal discloses a near-infrared quantitative analysis instrument for measuring glucose. (Abstract of Rosenthal). Rosenthal implies that different algorithms can be used, such as those that have 2,3,4, or 6 wavelengths. (column 4, lines 36- 61 and column 5, line 65 to column 6, line 11 of Rosenthal). Calibration constants are presented in these equations. It is well known in the art that these calibration constants are derived from experimental data sets that consist of the various wavelengths. Rosenthal does not teach that the data sets are augmented using cross-product terms. Braig et al. teaches an instrument for non-invasively measuring the concentration of glucose, dissolved carbon dioxide, ethyl alcohol and other blood constituents. (column 1, lines 7-17 of Braig et al.). Braig et al. discloses a method of determining the concentration of each blood constituent concentration using a polynomial equation that includes cross-product terms. (column 15, lines 31- 58 of Braig et al.). The equations of Braig et al. perform the same function as those presented by Rosenthal. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the equations of Braig et al. for the equations of Rosenthal since they are functionally equivalent and Rosenthal implies that formulas based on calibration can be used. The polynomial equations of Braig et al. use calibration constants to equate the data set and cross-products to the constituent concentration. The combination does not teach the use of forming a plurality of subsets, evaluating the

plurality of subsets, selecting a subset, and using the selected set to form an optimal calibration. Gozani teaches a non-invasive blood analyte concentration monitor which determines the blood glucose concentration using a linear or non-linear function. (column 18, line 30 to column 19, line 27 of Gozani). Gozani teaches that the optimal calibration coefficients for the equation can be determined using a Monte Carlo method. The use of the Monte Carlo method would provide the necessary calibration coefficients required by Gozani. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include the determination of the optimal calibration coefficients as disclosed by Gozani in the combination since the combination requires the determination of calibration coefficients and Gozani teaches such a method. The Monte Carlo method is a well known method that involves the use of forming a plurality of subsets which have randomly selected data and evaluating the subsets to achieve the optimal calibration coefficients. Rosenthal teaches using reliable data such as the "finger poke" measurement to calibrate the device. (column 6, lines 23-47 of Rosenthal). In regard to claim 2, Braig et al. teaches that second and third order terms can be used. (column 15, lines 31-53 of Braig et al.). In regard to claim 6, the combination is used to determine glucose. (Abstract of Rosenthal). In regard to claims 7-9, it is well known in the art to take measurements at various tissue sites to achieve a comprehensive calibration of a subject and to test the calibration. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to take measurements at various tissue sites to achieve a comprehensive calibration and to test the calibration. In regard to claims 10-14, it is well known in the

art to categorize low, high, and middle ranges when taking measurements to alert the operator of the patient's medical status. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination to include categorizing the ranges when taking measurements to alert the operator of the patient's medical status. The categories of ranges is dependent upon the desired accuracy of the device, the glucose level to be monitored (Rosenthal suggests between 40-500mg/dl), and the preference as to when an alert should be identified. This provides a clear suggestion that the categories of ranges can be modified and that the determination of the most appropriate categorization of ranges by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the art. In regard to claim 15, Rosenthal suggests that the surface temperature of the finger may be a parameter in the data set. (column 5, line 65 to column 6, line 12 of Rosenthal). In regard to claim 17, Rosenthal, Gozani, and Braig et al. disclose a microprocessor and memory for carrying out the invention's operations.

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent 5,606,164 to Price et al. discloses a method and apparatus for measuring the concentration of an analyte present in a biological fluid. Price et al. discloses a calibration procedure which includes detecting outliers using a variance-covariance matrix. U.S. Patent 4,883,953 to Koashi et al. discloses a method for measuring the concentrations of sugars in the near infrared which includes a linear

combination of absorbances at three wavelengths including cross-product terms. U.S. Patent 5,452,723 to Wu et al. discloses a spectrographic imaging device which uses Monte Carlo simulations.

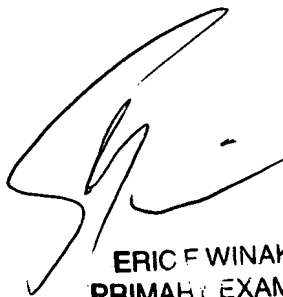
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Matthew Kremer
Examiner
Art Unit 3736
January 3, 2002



ERIC F WINAKUR
PRIMARY EXAMINER